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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,131

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03/03/2009

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,131	Applicant(s) OFER, DROR	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,29-57,102,103,155-159 and 161-163 is/are pending in the application.
- 4a) Of the above claim(s) 7,10-13,16-23,37-39,50-53,57,102,103 and 157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,14,15,24,25,29-36,40-49,54-56,155,156,158,159 and 161-163 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/04/2008</u> | 6) <input type="checkbox"/> Other: _____ |

Amendment filed 12/03/2008 is acknowledged. Claims 26-28,160 are canceled. Claims 1-25,29-57,102,103,155-159,161-163 are pending. Claims 7,10-13,16-23,37-39,50-53,57,102,103,157 remain withdrawn from consideration. Claims 1-6,8,9,14,15,24,25,29-36,40-49, 54-56,155,156,158,159,161-163 are under examination.

Upon consideration of the issues in this application and applicant's response, Examiner decided, instead of preparing comprehensive office action addressing all issues, to limit this office action to one issue that determines how the other main issues will be approached. This is the issue of whether the step "performing a plurality of assays" is directed to *in vitro* analytical assays or to *in silico* computational assays.

In response to rejection "E" under 112, second paragraph, applicant responds that the claimed invention includes both experimental and computational steps. Does it mean that the step of "performing a plurality of assays" is limited to *in vitro* analytical assays? From the disclosure in specification, it seems that, contrary, the assays are rather computational analysis of binding. See specification, paragraphs [0097],[0119], for example.

Clarification of this issue will determine different approach to analysis of prior art, as well as addressing the issue of non-statutory status of the invention.

If the assays are *in vitro* than the claims read on, for example, interaction of a target compound and any ligand. The latter will be viewed as inherently possessing any number of "substantially triangular" configurations as any molecular structure in solution

is to some extent conformationally limited on one side, and the term “substantially triangular” is vague enough to encompass any combination of three coordinates existing in the molecule of a ligand. Further, with respect to issue of non-statutory status of the invention, depending on the criticality of the step of assaying in otherwise computational method, the invention may still be considered non-statutory if the assay step is considered as pre-solution activity. See recent decision on *In re Bilski* (Fed. Cir., October 30, 2008) which clarifies that gathering data would not constitute a transformation of any article. A requirement simply that data inputs be gathered—without specifying how—is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs. *Bilski*, p. 27.

If the assays are *in silico*, then the problem of non-statutory status of the invention remains as the method is not tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing. A claimed process is patent-eligible under § 101 if it is tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing. Thus, the machine-or-transformation test is a two-branched inquiry: an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See *In re Bilski* (Fed. Cir., October 30, 2008). The use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility. Further, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.

Thus, the applicant is invited to clarify the issue of whether the step “performing a plurality of assays” is directed to *in vitro* analytical assays or to *in silico* computational assays.

Full response to the communication of 12/03/2008 will be provided thereafter.

Since this office action is intentionally incomplete and does not address all issues in the case, it is made non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin/

Primary Examiner, Art Unit 1631